REMARKS

Claims 1-32 were pending. Claims 30-32 were withdrawn by the Examiner as being directed to a non-elected invention. Claims 26 and 27 are canceled without prejudice. Claim 1 is amended herein. Support for the amendments is found throughout the specification at, *inter alia*, ¶46, ¶56 and the original claims. Claims 1-25 and 28-29 are pending. No claim is allowed.

The amendments to the claims are made solely to obtain expeditious allowance of the instant application and not for reasons related to patentability. Amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or amended claims. The amendments to the claims are fully supported by the application as filed.

Applicants believe that no new matter has been added by any of these amendments and the Examiner is respectfully requested to enter them.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 5-6, 11-13, 15-17, 19, 22-24, 26 and 28-29 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Baer et al (WO 00/61806). According to the Examiner, Baer teaches a method that includes contacting a sample with probe molecules bonded to a solid support, biotinylated nucleic acid probe molecules bound to avidin-labeled support to which nucleic acid components bind, and antibody molecules conjugated with biotin bound to avidin-labeled support to which protein components bind. The Examiner asserts that Baer encompasses nucleic acid and protein components contained in a sample becoming bound to solid support where the solid support to which the nucleic acids bind are distinct from the solid supports to which protein components are bound. Applicants traverse this rejection.

Baer fails to anticipate the claimed methods as it fails to set forth each and every element of the methods. The test for anticipation is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). "A claim is anticipated **only** if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (citations omitted) (emphasis added). Baer fails to fulfill this standard.

The claimed methods are drawn to the isolation of nucleic acids and proteins using properties other than the nucleic sequence and binding specificity, respectively. *See, e.g.*, the

Specification at ¶¶46 and 56. In contrast, Baer discloses the isolation of nucleic acids in a sequence-dependent manner and the isolation of proteins in a binding-specificity dependent manner. In particular, the example highlighted by the Examiner, *i.e.,* Example 2, discloses the isolation of a specific RNA, *i.e.*, HER-2/neu mRNA, and a specific protein, HER-2/neu protein. In fact, the entirety of the Baer disclosure results to methods of isolation based on sequence-dependent nucleic acid binding or the specific capture of a particular protein. *See, e.g.,* Baer at page 3, lines 5-10, page 6, lines 24-31, and page 9, lines 25-29. Baer is absolutely silent regarding methods of isolating nucleic acids in a sequence-independent manner and isolating proteins using only chromatographic interactions. As Baer fails to teach these elements, it fails to anticipate the claimed methods.

For at least these reasons, the rejection under § 102(b) is overcome and may be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 2, 7-10, 12-14 and 18-20 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baer et al (WO 00/61806) in view of Riol et al (*Analytical Biochemistry*, (1999) 275, 192-201). Briefly, the Examiner asserts that Baer teaches a method that includes contacting a sample with probe molecules bonded to solid supports as well as teaching antibody molecules conjugated with biotin bonded to avidin-labeled supports to which protein components bind. The Examiner alleges that Riol teaches the isolation of genomic DNA from lymphocytes as well as teaching the optimized method to isolate total DNA, RNA and protein components from limited amounts of biological materials. Thus, the Examiner asserts it would be obvious to one of ordinary skill in the art to combine the teachings of Baer and Riol to result in the claimed methods.

Claims 1, 4, 21, 24 and 25 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baer et al (WO 00/61806) in view of Hornes et al (US Patent No. 5,512,439). According to the Examiner, Hornes teaches the isolation of RNA on a solid support but does not teach specifically the RNA and DNA bound to different solid supports in different steps. The Examiner also asserts that Hornes teaches the use of magnetic beads for isolation of mRNA and ssDNA as well as magnetic beads carrying carboxyl groups.

Claims 1 and 27 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Baer et al (WO 00/61806) in view of Nobel et al (US Patent No. 5,084,169). The Examiner asserts that Nobel teaches a method for separating proteins from a lysed cell

mixture using magnetizable ion exchange particles and thus a surface capable of having a chromatographic interaction.

Claims 1, 3, 6-12, 17-20, 22-24, 26 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ibrahim (U.S. Patent No. 6,919,200) in view of Riol et al (*Analytical Biochemistry*, (1999) 275, 192-201). Briefly, the Examiner asserts that Ibrahim teaches a method of isolating nucleic acid and protein from each other in a sample using a sample collection assembly, the solid support, as well as teaching the use of different solid supports for nucleic acid and protein component purification. The Examiner appears to rely on Riol for its teaching of isolating nucleic acids and proteins from the same sample.

Applicants traverse these rejections.

Applicants respectfully submit that none of the cited combination of references render the claimed methods *prima facie* obvious. First, the cited combination of references must teach or suggest each and every limitation of the claimed invention(s). Then, the obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Applicants note that if a modification changes the principle of operation of a reference, then there cannot be said that a reasonable expectation of success exists.

Baer and Riol

The cited combination of Baer and Riol fail to render the claimed method *prima facie* obvious because the references fail to teach or suggest each and every element and combining Baer with Riol improperly changes the principle of operation of the Baer invention. First, Baer and Riol fail to teach each and every element of the claimed invention. As discussed above, Baer disclosure is limited to the isolation of nucleic acid and protein based on specific nucleic acid sequence or protein identity. Riol fails to cure Baer's deficiencies as Riol merely addresses traditional means of isolation nucleic acids and proteins using organic solvents. Neither reference alone or in combination teach or suggest the use of non-specific binding properties for nucleic acid and protein component separation on a plurality of solid supports. Moreover, combining Baer with Riol to result in the claimed invention improperly changes the Baer from a method to specifically isolate particular nucleic acid sequence and proteins to one that non-specifically isolates most or all nucleic acid or protein components from a sample.

Baer and Hornes

Likewise, Hornes fails to remedy the deficiencies in Baer and thus the combination of Baer and Hornes fails to render the claimed methods *prima facie* obvious. Hornes, like Baer,

discloses the isolation of specific mRNA or ssDNA using a specific oligonucleotide. For example, Hornes states:

> B. Kit for Isolation of Specific mRNA or ssDNA from Sample
>
> (a) Magnetic particles according to the invention carrying a specific oligonucleotide and …

Hornes at col. 12:5-7. The language in column 4 relied upon by the Examiner describes the use of bead with low non-specific binding properties for the attachment of the specific oligonucleotide used for isolation. *See, e.g.*, Hornes at col. 4: 32-63. In sum, neither Baer nor Hornes addresses the use of non-specific binding properties to isolate nucleic acid and protein components from a sample using a plurality of solid supports as in the claimed methods.

Baer and Nobel

As with Riol and Hornes, Nobel fails to cure the deficiencies in Baer. Nobel addresses protein purification only. Nobel is completely silent as to the isolation of nucleic acid components in a sequence-independent manner using a plurality of supports from a sample as in the claimed methods.

In sum, Baer in combination with any one of Roil, Hornes or Nobel fails to render the claimed methods *prima facie* obvious because these references fail to teach or suggest the isolation of the nucleic acid and protein components in a sequence-independent or specific protein identity-independent manner or provide sufficient guidance such that a person of ordinary skill in the art would have a reasonable expectation of success in modifying the cited references to result in the claimed methods.

Ibrahim and Riol

The combination of Ibrahim and Riol also fails to render the claimed methods *prima facie* obvious. Ibrahim discloses the isolation of either a nucleic acid component or a protein component from a sample using a single solid support, *i.e.*, the wand. Nothing in Ibrahim teaches or suggests using a plurality of supports to isolate one or more nucleic acid component and a protein component from a sample as in the claimed methods. The Examiner cites Ibrahim as disclosing a plurality of solid supports in the following:

> The reservoir tube **6** serves as a reservoir for collecting samples, washing the nucleic acids, proteins, antibodies or antigens, and eluting the captured nucleic acid or proteins or other molecules.

Ibrahim at col. 6:51-54. This disclosure relates to the reservoir rather than the solid support that actually captures a particular component of the sample. Nothing in Ibrahim teaches or suggests the use of a plurality of solid supports for isolation of nucleic acids and proteins as in the claimed methods. Riol's disclosure is silent on the use of solid supports as it is limited to

isolation of nucleic acids and proteins using organic solvents. Thus, the combination of Ibrahim and Riol fails to teach each and every element of the claimed methods and thus cannot render the claimed methods obvious.

For at least these reasons, Applicants respectfully submit that the rejections are overcome and may be withdrawn.

CONCLUSION

In view of the amendments and remarks applicants believe that the application is now in condition for allowance. Prompt and favorable consideration of this response is respectfully requested. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (541) 335-0203.

Respectfully submitted,

Date: February 11, 2008

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